IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

TAMMY PIZZITOLA, *Plaintiff*,	§	
v.	§	CIVIL ACTION NO. 4:20-CV-02256
ETHICON, INC. and JOHNSON & JOHNSON, *Defendants*.	§	

ORDER

Before the Court is the Motion to Exclude Certain General Opinions of Bruce Rosenzweig, M.D. filed by Defendants Ethicon, Inc. and Johnson & Johnson. (Doc. No. 160). Plaintiff Tammy Pizzitola has filed a response in opposition and Defendants have replied. (Doc. Nos. 169, 173). The Court hereby **grants** in part and **denies** in part the motion.

I. Legal Standard

Defendants' motion was filed primarily under the principles set in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993) and *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999). *Daubert*'s holdings have been summarized as follows:

> Reliable testimony must be grounded in the methods and procedures of science and signify something beyond "subjective belief or unsupported speculation." *Daubert*, 509 U.S. at 590, 113 S.Ct. 2786. The inferences or assertions drawn by the expert must be derived by the scientific method. *Id.* In essence, the court must determine whether the expert's work product amounts to "'good science.'" *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1315 (9th Cir. 1995) ("Daubert II") (quoting *Daubert*, 509 U.S. at 593, 113 S.Ct. 2786). In *Daubert*, the Supreme Court outlined factors relevant to the reliability prong, including: (1) whether the theory can be and has been tested; (2) whether it has been subjected to peer review; (3) the known or potential rate of error; and (4) whether the theory or methodology employed is generally accepted in the relevant scientific community. *Daubert*, 509 U.S. at 593–94, 113 S.Ct. 2786. The Supreme Court emphasized the "flexible" nature of this inquiry. *Id.* at 594, 113 S.Ct. 2786. As later confirmed in *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 119 S.Ct. 1167, 143 L.Ed.2d 238 (1999): "*Daubert*'s list of specific factors neither

> necessarily nor exclusively applies to all experts or in every case. Rather the law grants a district court the same broad latitude when it decides how to determine reliability as [the court] enjoys in respect to its ultimate reliability determination." *Id.* at 141–42, 119 S.Ct. 1167.

Abarca v. Franklin Cty. Water Dist., 761 F. Supp. 2d 1007, 1021 (E.D. Cal. 2011).

While *Daubert* attacks usually focus on a witness' reliability, some courts have also included an attack on a witness' qualification (or lack thereof) under the *Daubert* umbrella. Defendants' motion has the elements of both.

II. Prior *Daubert* Rulings of the MDL Court

At the onset, the Court notes that Defendants assert in their motion that both sides have agreed to be bound by the *Daubert* rulings previously made by the MDL Court. (Doc. No. 159). While the parties stipulated to be bound by those rulings for purposes of the trial in this case, each side apparently reserved the right to appeal those rulings at the appropriate time post-judgment. This, of course, puts this Court in a somewhat interesting position. It can reject or accept such stipulation and then later be second-guesses on appeal for a ruling it did not make or reject the stipulation that both sides have endorsed. While this Court questions whether one can agree to be bound by a ruling and then appeal it, it accepts the parties' stipulation.

That being the case, there are a number of objections contained in Defendants' motion that this Court need not address as they were already addressed in the MDL and were repeated by the Defendants here only as a means of preserving the Defendants' objection to the ruling.

III. Defendants' Motion

Dr. Rosenzweig is an assistant professor of obstetrics and gynecology at Rush University Medical College in Chicago. In addition to completing medical school at the University of Michigan and an Ob/Gyn residency in Chicago, he has had additional training in pelvic surgery,

urogynecology, and urodynamics. Thus, he is familiar with many of the pertinent areas to this lawsuit.

Defendants seeks to limit Dr. Rosenzweig's testimony in such a fashion that he should not be allowed to testify about:

1. General opinions concerning the Prolift +M;
2. Non-synthetic mesh procedures being a safer alternative;
3. Alternative synthetic designs being safer;
4. The manner in which the TVT-O mesh is cut;
5. The reporting duties owed by a device manufacturer to FDA and in physician training; and
6. The alleged failure to warn of the information contained in the MSDS for the polypropylene resin used in the mesh.

The MDL Court has already ruled that Dr. Rosenzweig cannot: (1) testify about marketing; (2) offer legal conclusions; (3) opine about Ethicon's knowledge and corporate conduct; and (4) provide narrative summaries of Defendants' documents. It denied Defendants' exclusion motions as to degradation/fraying and Prolene particle loss and as to the reliability of Dr. Rosenzweig's opinions concerning PVDF as an alternative, safer design.

IV. Prolift +M Testimony

The first issue appears to be the simplest. Dr. Rosenzweig is hereby precluded from generally testifying in any fashion about the Prolift +M product. His report does not address this product. This issue is less of a *Daubert* issue and more of one that falls under the auspices of the Rules of Civil Procedure. Rule 26(a) states that an expert's report must contain "(i) *a complete statement of all opinions* the witness will express and the basis and reasons for them; (ii) the facts or data considered by the witness in forming them," and "(iii) any exhibits that will be used

to summarize or support them. . . ." Fed. R. Civ. P. 26(a)(2)(B) (emphasis added). A party's failure to provide timely expert disclosures under Rule 26 precludes the party from "us[ing] the information or witness to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless." *Davis v. Davis*, No. 2:12-CV-166, 2017 WL 896299, at *4 (S.D. Tex. Mar. 7, 2017) (quoting Fed. R. Civ. P. 37(c)(1)).

In response to Defendants' motion, Plaintiff does, however, draw a few distinctions to which Defendants appear to agree. First, both sides agree that Dr. Rosenzweig may rely on Dr. Garely's general report concerning the Prolift +M. The Court warns both sides that there is a significant difference between an expert relying on a report and an expert parroting the opinion of another expert. The Court will not allow the latter. No expert will be allowed to "parrot" another expert's report, opinions, or testimony. Second, the parties appear to agree that, as a case-specific expert, Dr. Rosenzweig will be allowed to offer case-specific causation opinions.

V. Design Alternatives

A. Non-Synthetic Mesh Alternatives

As this Court notes in other orders, this category of testimony in the context of a *Daubert*/relevance challenge tees up the most difficult of the currently raised *Daubert* topics. It involves a variety of different approaches and "devices" and a number of different procedures. The Court will address the two easiest issues first. The Court excludes the testimony concerning the "Burch procedure" at least as far as it is being proffered to support a design defect claim. It is not an alternative design of any product. In fact, it is not a product at all.

Plaintiff argues that this evidence is admissible as relevant in a risk versus utility analysis. She is mistaken, however. While a design defect claim has in its roots a risk versus utility comparison, a completely different product or approach is not a competitor. The fact that

there were safer medical procedures might be relevant if the claim were being made against the treating physician, but not here. A showing that a different medical procedure is safer does not affect whether a product has utility and/or risks. The Texas statute that governs design defects makes this abundantly clear. It states in pertinent part, "…safer alternative design means a *product* design other than the one actually used…." Tex. Civ. Prac. & Rem. § 82.005 (emphasis added). A procedure is not a product or a product design. Moreover, whether a procedure is safer than the implantation of a device is medical judgment as to which is more appropriate for a given patient, but it does not impact whether a product is unreasonably dangerous.

The court in *Mullins v. Johnson & Johnson* made this very point:

> Evidence that a surgical procedure should have been used in place of a device is not an alternative, feasible design in relation to the TVT. Whether an alternative procedure could have been preformed without the use of the TVT does nothing to inform the jury on the issue of an alternative, feasible design for the TVT. Instead, alternative surgeries or procedures raise issues wholly within the context of what a treating physician has recommended for patients based on the individual needs and risk factors associated with individual patients. In other words, alternative surgeries or procedures concern the medical judgment of the doctors who use TVT devices to treat stress urinary incontinence ("SUI"); other surgeries or procedures do not inform the jury on how the TVT's design could have feasibly been made safer to eliminate the risks that caused the plaintiffs' injuries.

236 F. Supp. 3d 940, 943 (S.D.W. Va. 2017) (citing *Talley v. Danek Med., Inc.*, 179 F.3d 154, 162 (4th Cir. 1999) (interpreting Virginia law)).

The same can be said for any testimony concerning autologous grafts—procedures in which the patient's own tissues are removed and fashioned into a sling and reused in a different part of the patient's own body.

The testimony that presents the closer call is that which discusses the use of xenografts (grafts made with animal tissue) and allografts (grafts fashioned from human donor tissue). These grafts are not medical devices and as such are not subject to the same regulatory scheme

as the products under scrutiny here. Courts have not been uniform in their approach concerning these biologic alternatives. Some have merely considered their end use or function and, having concluded they perform the same function of a mesh device, hold that they can be considered as alternative "products." *See e.g., Bell v. Ethicon, Inc.*, 2021 WL 1111071, at *18–19, (S.D. Tex. 2021); *Messina v. Ethicon, Inc.*, 2020 WL 7419586, at *4 (M.D. Fla. 2020).

Other courts have found that, due to the fact that xenografts and allografts are not man-made artificial products, they are governed by a completely different FDA scheme and therefore are subject to a completely separate and distinct set of regulations. *Labiche v. Johnson & Johnson*, 2021 WL 3719554, at *2 (S.D. Tex. 2021); *Salinero v. Johnson & Johnson*, 2019 WL 7753453 (S.D. Fla. 2019); *Hosbrook v. Ethicon, Inc.*, 2020 WL 5214644 (S.D. Ohio 2020). They conclude, therefore, that they cannot be considered a safer alternative design.

The primary question seems to be reduced to whether allografts and xenografts are comparable products to those under attack? Stated differently, since the natural material performs the same function as Defendants' synthetic material, the Plaintiff should be able to use the natural material in a safer comparable product analysis. Or, if they are not "products" as that term is generally understood, and instead are basically part of a completely different medical procedure, should all the related testimony be excluded?

While this presents a close question, this Court holds on the basis of the record before it, that while xenografts and allografts may ultimately perform the same function, they are not comparable artificial "devices," and as such they cannot be used as the comparator in a feasible, safer alternative design context.

> The choice of a surgery over a device is a matter of medical judgment of treating doctors, not whether there is a safer alternative design for the product. Thus, the Willets must provide "sufficient evidence to identify a comparable product or design concept" to generate a jury question on the sufficiency of the alternative,

> feasible design. I agree with the defendants that allografts and xenografts are not "comparable products" or "comparable design concepts" to the Prosima device, when, for example, allografts are regulated by the FDA as human tissues for transplantation, *see* 21 C.F.R. Part 1271, and xenografts are regulated as biological products for transplantation, *see* FDA Guidance Document: Source Animal, Product, Preclinical, and Clinical Issues Concerning the Use of Xenotransplantation Products in Humans at 7. Neither is classified as a medical device, like Prosima.

Willet v. Johnson & Johnson, 465 F. Supp. 3d 895, 907–8 (S.D. Iowa 2020).

According to the record before the Court, the material contained in xenografts or allografts is natural "fiber" or "material." It is not "designed" by anyone. The products under scrutiny here were designed by someone and therefore theoretically some individual could, and may already have, come forward with an artificial product that is designed in a safer fashion than the Defendants' products. Such a product, if, and when, it exists would be a fair comparator. That being said, the choice to use an artificial device (which falls under a completely different design, approval, and regulatory process) over a natural product is a medical decision, as is what procedure the physician wants to perform and to which the patient consents.

Having made this ruling, the Court finds the need to address one factor that was alluded to in the *Willet* opinion. In that case, it was suggested that a defendant made the argument that its product was the safest means to treat a certain condition. *Willet*, 465 F. Supp. 3d at 907. That statement may or may not be accurate, but it does raise one important point. While this Court has held that natural products cannot be used in the design defect context, Defendants are cautioned that if they take the position in this case that their product is the "safest means," the Court will certainly allow Plaintiff to counter that claim if the evidence supports that these natural products are indeed safer.

B. Alternative Synthetic Design

Defendants contend that Dr. Rosenzweig should not be allowed to opine that a "TVT-O" device made with a lighter-weight and more microporous mesh would be much safer. The basis for the objection is that at the time of Plaintiff's procedure, no such product existed on the market. Plaintiff responds by referring this Court to a number of out of state decisions that appear to allow this testimony. She cites this Court to one decision here in the Southern District of Texas that FDA approval is not a prerequisite for a product to be a safer alternative.

This Court has addressed this issue at length in other *Daubert* rulings and does not feel the need to repeat its reasoning again here. Suffice it to say, in the field of prescription drugs and medical devices, FDA approval is the key to making such a device feasible and available for physicians to use outside of an experimental setting. Defendants claim, and Plaintiff does not seem to dispute it, that such a device that is anticipated by this testimony is still not FDA-approved today. While the MDL Court may have generally allowed such testimony, this Court is not bound by that decision when the relevance or, in this case the irrelevance, is a matter of Texas substantive law. In this regard, Defendants' motion to exclude is granted.

VI. Manner In Which the TVT-O Mesh Is Cut

Defendants' motion seeks to preclude Dr. Rosenzweig from testifying that the manner in which the mesh is cut makes the product unreasonably dangerous. Their motion points out there are two methods of cutting the mesh: mechanical or laser. It also points out that Dr. Rosenzweig has opined that both methods carry risks to the end user. He opines that the laser cut leaves the mesh too stiff, and thus more dangerous, than the mechanical cut. He also opines that the mechanical cut mesh can curl, fray, and lose pore size and particles, which renders it more dangerous than the laser cut. Thus, according to Dr. Rosenzweig, the mesh is defective

regardless of the manner in which it is cut. The only difference is the "mechanisms" that cause the complications. More importantly, perhaps, Defendants point out that no one links any of the Plaintiff's injuries to the manner in which the mesh was cut. Plaintiff responds, unsurprisingly, that these opinions are admissible to prove that the product was unreasonably dangerous and cites this Court to a number of cases from other jurisdictions that denied the Defendants' objections as to reliability or that held that this was a matter more appropriately addressed in a healthy cross-examination as opposed to a *Daubert* motion.

This Court finds that again this question is more a matter of relevance than it is a question of expertise or reliability. Here, Plaintiff has abandoned her claims of manufacturing defect, strict liability product defect, and breach of warranty. Thus, the remaining strict liability claims are grounded in design defects or defective warnings/labeling.

Texas law requires in design defect cases that the design defect that made the product unreasonably dangerous be the producing cause of the injury. *In re DePuy Orthopaedics, Inc., Pinnacle Hip Implant Prod. Liab. Litig.*, 888 F.3d 753, 765 (5th Cir. 2018). Other design defects are irrelevant. With respect to marketing defects, Plaintiff must prove the warnings were defective and the defect was the producing cause of the injury. *Ackermann v. Wyeth Pharm.*, 526 F.3d 203, 208 (5th Cir. 2008). Since Plaintiff does not claim that Dr. Rosenzweig (or any other qualified expert) connects the manner in which the mesh was cut to any injury suffered by Plaintiff, there is no relevance to this testimony. Irrelevant testimony is not going to be allowed.

VII. Opinions Regarding Adverse Event Reporting and Physician Training

Defendants object to the purported testimony of Dr. Rosenzweig to the extent he opines on duties that Ethicon owes as a product manufacturer, including its reporting of adverse events. Plaintiff concedes that she will not solicit any testimony from Dr. Rosenzweig concerning

Ethicon's collection of adverse events but argues that he should be able to opine that its reporting was "incomplete, inaccurate, and misleading."

The Court hereby excludes any testimony concerning adverse event reporting and Ethicon's compliance or non-compliance with any FDA requirements. Plaintiff has not shown that Dr. Rosenzweig has any expertise in this area. The Court further excludes any testimony concerning the level of training the Defendants provided to physicians. First, while the Court recognizes that some pharmaceutical and device manufacturers sometimes provide training sessions and manuals to doctors, it is not the role of companies to train medical doctors in how to practice medicine. Most doctors go through years of medical school, residency, and some even go through fellowships to perfect their skills as doctors. Second, and perhaps more importantly, no complaints have been made that Dr. David Kent, the treating physician in this case, was improperly trained or that his care fell below the standard of care in any aspect. Thus, how a device company did or did not train a doctor is completely immaterial.

To the extent these opinions are included in Dr. Rosenzweig's report and are not barred by any agreements of the parties or the MDL Court's order, Dr. Rosenzweig is able to comment on the risks and benefits of the surgery in question and whether those risks are contained in the IFU or other pertinent materials. He may also address whether the Defendants had prior complaints about these risks based upon the adverse events that had been reported to it. Having said this, this last holding is not a green light for Dr. Rosenzweig to give his own narrative summary of the contents of Ethicon's files.

VIII. MSDS

The MDL Court ruled that Dr. Rosenzweig could rely upon the Material Safety Data Sheets (MSDS) concerning polypropylene (and its statements about "strong oxidizers") in his

testimony. The Defendants have agreed to be bound by the MDL ruling (Doc. No. 159), so this Court need not revisit this issue.

IX. Conclusion

Defendants' Motion to Exclude Certain General Opinions of Bruce Rosenzweig, M.D. is **granted** in part and **denied** in part. The stipulation concerning the prior rulings of the MDL Court is adopted. The motion to exclude any testimony by Dr. Rosenzweig concerning Prolift +M is **granted**. The motion to exclude his testimony as to alternative safer designs (as explained above) is **granted**. The motion to exclude all opinions and conclusions as to Defendants' duties and compliance with FDA adverse reaction reporting is **granted**. The motion to exclude as it pertains to Dr. Rosenzweig's testimony concerning training for doctors and concerning the manner in which the mesh is cut is **granted**. The motion to exclude Dr. Rosenzweig's testimony concerning the polypropylene MSDS is **denied**.

SIGNED at Houston, Texas this 7th day of October, 2022.

Andrew S. Hanen
United States District Judge